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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,596	SPIES ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2010 and 10 January 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *16-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 7-15* is/are rejected.

7)☒ Claim(s) *5 and 6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Appendices I-IV*.

DETAILED ACTION

Claims 1-25 are pending in the instant application.

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 7/9/2010 is acknowledged.

Claims 16-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/9/2010.

An examination on the merits of claims 1-15 follows.

Specification

The disclosure is objected to because of the following informalities:

1. Page 62, line 23 refers to Figure 1; however, the application does not contain drawings.

2. The specification refers to nucleotides 54-3675 of the sequence set forth in SEQ ID NO: 3 (page 3, line 26; page 4, line 8), yet SEQ ID NO: 3 only sets forth nucleotides 1-3584.

Appropriate correction is required.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See page 9, line 17.

The use of the trademark GENBANK (page 62, line 11), SUPERFECT (page 23, lines 11 and 29), and ADEASY (page 62, line 28) has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claims 4, 9 and 13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 4 depends from claim 1, which requires an expression cassette comprising from 5' to 3' the following elements: a CMV promoter sequence, a CMV enhancer sequence, a CMV intron A sequence, a heterologous nucleic acid sequence, and a polyadenylation site, wherein the promoter is operably linked to the heterologous nucleic acid sequence. The sequence of SEQ ID NO: 3 comprises an expression cassette containing each of the recited elements except for the heterologous nucleic acid sequence (e.g., specification, Example 1). The sequence of SEQ ID NO: 3 is the sequence of plasmid pCRXA20, which contains a region that allows for cloning of a heterologous gene into the vector; however, the vector sequence of SEQ ID NO: 3 does not contain this heterologous gene sequence (e.g., specification, paragraph [0014] and Example 1). The sequence of SEQ ID NO: 3 contains the

following from 5' to 3': a CMV enhancer sequence, a CMV promoter sequence, a CMV intron A sequence (which can be considered as comprising an enhancer sequence of intron A and further comprising additional intron A sequence 3' to the intron A enhancer sequence), a multiple cloning site, and a polyadenylation site (e.g., Example 1; alignments of GenBank Accession No. M60321 with SEQ ID NO: 3 as shown in Appendices I-III). Thus, the expression cassette of SEQ ID NO: 3 does not include every limitation of the parent claim.

Claims 9 and 13 depend from claim 4 and are objected to for the same reason applied to claim 4. Although claims 9 and 13 provide further limitations to claim 1 with regard to the host cell, they do not include every limitation of claim 1 with regard to the expression vector.

Claims 5 and 10 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 5 depends from claim 1, which requires an expression cassette comprising from 5' to 3' the following elements: a CMV promoter sequence, a CMV enhancer sequence, a CMV intron A sequence, a heterologous nucleic acid sequence, and a polyadenylation site, wherein the promoter is operably linked to the heterologous nucleic acid sequence. The sequence of nucleotides 1-1653 of SEQ ID NO: 3 comprises an expression cassette containing each of the recited elements except for the heterologous nucleic acid sequence (e.g., specification, Example 1). The sequence of SEQ ID NO: 3 is the sequence of plasmid pCRXA20, which contains a region that allows for cloning of a heterologous gene into the vector; however, the vector sequence of SEQ ID NO: 3 does not contain this heterologous

gene sequence (e.g., specification, paragraph [0014] and Example 1). The sequence of SEQ ID NO: 3 contains the following from 5' to 3': a CMV enhancer sequence, a CMV promoter sequence, a CMV intron A sequence (which can be considered as comprising an enhancer sequence of intron A and further comprising additional intron A sequence 3' to the intron A enhancer sequence), a multiple cloning site, and a polyadenylation site (e.g., Example 1; alignments of GenBank Accession No. M60321 with SEQ ID NO: 3 as shown in Appendices I-III). Thus, the expression cassette of nucleotides 1-1653 of SEQ ID NO: 3 does not include every limitation of the parent claim.

Claim 10 depends from claim 5 and is objected to for the same reason applied to claim 5. Although claim 10 provides further limitations to claim 1 with regard to the host cell, it does not include every limitation of claim 1 with regard to the expression vector.

Claims 6, 11 and 14 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 6 depends from claim 1, which requires an expression cassette comprising from 5' to 3' the following elements: a CMV promoter sequence, a CMV enhancer sequence, a CMV intron A sequence, a heterologous nucleic acid sequence, and a polyadenylation site, wherein the promoter is operably linked to the heterologous nucleic acid sequence. The sequence of SEQ ID NO: 3 comprises an expression cassette containing each of the recited elements except for the heterologous nucleic acid sequence (e.g., specification, Example 1). The sequence of SEQ ID NO: 3 is the sequence of

plasmid pCRXA20, which contains a region that allows for cloning of a heterologous gene into the vector; however, the vector sequence of SEQ ID NO: 3 does not contain this heterologous gene sequence (e.g., specification, paragraph [0014] and Example 1). The sequence of SEQ ID NO: 3 contains the following from 5' to 3': a CMV enhancer sequence, a CMV promoter sequence, a CMV intron A sequence (which can be considered as comprising an enhancer sequence of intron A and further comprising additional intron A sequence 3' to the intron A enhancer sequence), a multiple cloning site, and a polyadenylation site (e.g., Example 1; alignments of GenBank Accession No. M60321 with SEQ ID NO: 3 as shown in Appendices I-III). Thus, the expression cassette of SEQ ID NO: 3 does not include every limitation of the parent claim.

Thus, the expression cassette of SEQ ID NO: 3 does not include every limitation of the parent claim. Claims 11 and 14 depend from claim 6 and are objected to for the same reason applied to claim 6. Although claims 11 and 14 provide further limitations to claim 1 with regard to the host cell, they do not include every limitation of claim 1 with regard to the expression vector.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8-14 are rejected under 35 USC § 101 because the claimed invention is directed to non-statutory subject matter. The claimed "cell" is present or intended to be present in a human being, which is non-statutory subject matter (specification, paragraphs [0124] and

[0182]). As such, the recitation of the limitation "isolated" would be remedial. See 1077 O.G. 24, April 21, 1987.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 9 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is vague and indefinite in that the metes and bounds of the phrase "wherein the expression cassette comprises nucleotides 54-3675 of the sequence set forth in SEQ ID NO: 3" are unclear. The phrase is unclear in that SEQ ID NO: 3 only contains nucleotides 1-3584. Thus, nucleotides 3585-3675 are not defined by the sequence of SEQ ID NO: 3. The specification discloses that SEQ ID NO: 3 is a DNA sequence for pCRXA20 (e.g., paragraph [0014]). Example 1 provides a further description of the pCRXA20 vector of SEQ ID NO: 3 and again indicates that the sequence is 3584 nucleotides. Because the specification does not disclose the identity of nucleotides 3585-3675, the metes and bounds of the claim are wholly unclear.

Claims 9 and 13 depend from claim 4 and are rejected for the same reason applied to claim 4.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 9 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims require the expression cassette to comprise nucleotides 54-3675 of the sequence set forth in SEQ ID NO: 3.

The specification discloses that SEQ ID NO: 3 is a DNA sequence for pCRXA20 (e.g., paragraph [0014]). Example 1 provides a further description of the pCRXA20 vector of SEQ ID NO: 3 and again indicates that the sequence is 3584 nucleotides. The specification does not describe nucleotides 3585-3675 of SEQ ID NO: 3.

Accordingly, no description is provided of nucleotides 3585-3675 of SEQ ID NO: 3. Thus, one would have recognized that Applicant was not in possession of the claimed invention for claims 4, 9 and 13, which require nucleotides 3585-3675 of SEQ ID NO: 3.

Claims 4, 9 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The claims require an expression cassette comprising nucleotides 54-3675 of the sequence set forth in SEQ ID NO: 3. The nature of the invention is complex in that the claim requires nucleotides 3585-3675 of SEQ ID NO: 3, yet these nucleotides are not present in the sequence set forth in SEQ ID NO: 3 in the originally filed specification.

Breadth of the claims: The claims are narrowly drawn to require nucleotides 54-3675 of SEQ ID NO: 3.

Guidance of the specification and existence of working examples: The specification discloses that SEQ ID NO: 3 is a DNA sequence for pCRXA20 (e.g., paragraph [0014]). Example 1 provides a further description of the pCRXA20 vector of SEQ ID NO: 3 and again indicates that the sequence is 3584 nucleotides. The specification does not teach the sequence of nucleotides 3585-3675 of SEQ ID NO: 3.

Predictability and state of the art: It would have been unpredictable to make a nucleic acid molecule that lacks defined structure.

Amount of experimentation necessary: Experimentation would not be successful in determining the sequence of nucleotides 3585-3675 of SEQ ID NO: 3, because these nucleotides

are not taught by the specification in any way. The absence of this teaching would not have been overcome by experimentation, the skill of one in the art, or the teachings of the prior art.

In view of the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. Therefore, claims 4, 9 and 13 are not are not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 8, 12 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Thudium et al (US Patent Application Publication No. 2005/0079488 A1; see the entire reference).

Regarding claims 1 and 15, Thudium et al teach a composition comprising an expression vector comprising an expression cassette, where the expression cassette comprises from 5' to 3' the following elements: a CMV promoter sequence, a CMV enhancer sequence, which can be part of an intron A sequence, a CMV intron A sequence from the CMV major immediate early gene, a heterologous nucleic acid sequence, and a polyadenylation site, where the promoter is

operably linked to the heterologous nucleic acid sequence (e.g., paragraphs [0006]-[0007], [0017], [0064], [0066], [0076], [0085], [0096]-[0098]; Example 1).

Regarding claim 2, Thudium et al teach the vector where the CMV intron A sequence has a deletion (e.g., paragraphs [0047]-[0052] and [0077]-[0079]). Thudium et al teach that the intron A fragment of CMV IE1 intron A has the sequence of SEQ ID NO: 1 (e.g., page 5). SEQ ID NO: 1 is 838 nucleotides in length, and the intron sequence GT...AG spans nucleotides 1-824 (e.g., Figure 1A). The claimed deletion of about base 1513 to about base 1736 is based on the number of intron A as nucleotides 1265-2088. This corresponds to a deletion of about 249 to about 472 of the sequence of Thudium et al. Thudium et al teach intron A fragments that retain at least up to the initial 7 nucleotides of the intron A region, and at least 25 nucleotides of the 3'-region of intron A, where any number of additional nucleotides may be present at the 5' and 3' ends of the intron to create internal deletions of any number of nucleotides (e.g., paragraphs [0077]-[0079]). Thus, Thudium et al teach a deletion of about 249 to about 472 (instant 1531 to 1736) of the sequence of intron A.

Regarding claim 3, Thudium et al teach the vector, where the heterologous nucleic acid encodes a cancer antigen (e.g., paragraphs [0085] and [0091]).

Regarding claims 8 and 12, Thudium et al teach a host cell comprising the vector, where the host cell is an E. coli host cell or a mammalian host cell (e.g., paragraphs [0063], [0100] and [0102]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thudium et al (US Patent Application Publication No. 2005/0079488 A1; see the entire reference) in view of Wang et al (US Patent No. 6,518,256 B1; see the entire reference).

The teachings of Thudium et al are described above and applied as before.

Thudium et al do not teach the expression vector, where the cancer antigen is encoded by the nucleotide sequence of SEQ ID NO: 6.

Wang et al teach vaccines for immunotherapy of lung cancer comprising DNA molecules encoding a lung tumor protein, including a tumor protein encoded by the polynucleotide sequence of SEQ ID NO: 347 (e.g., Abstract; column 1, line 59 to column 2, line 27; column 2, lines 59-61; column 13, line 55 to column 14, line 41). Wang et al teach that the sequence of

SEQ ID NO: 347 is a determined full-length cDNA sequence for L523S (e.g., column 13, lines 44-45). The nucleic acid sequence of SEQ ID NO: 347 is identical to instant SEQ ID NO: 6 (see the attached alignment in Appendix IV). Wang et al teach that the polynucleotide may be cloned into a variety of cloning vectors, including expression vectors, using established recombinant DNA techniques (e.g., column 18, lines 16-28; claims 1-3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the expression vector encoding a heterologous cancer antigen of Thudium et al to include the nucleic acid sequence encoding L523S (SEQ ID NO: 347), taught by Wang et al, as the sequence encoding the cancer antigen, because Thudium et al teach it is within the ordinary skill in the art to include a heterologous nucleic acid sequence encoding a cancer antigen and Wang et al teach that the nucleic acid sequence of SEQ ID NO: 347 encodes a lung cancer antigen.

One would have been motivated to make such a modification in order to receive the expected benefit of providing an expression vector capable of expressing the lung cancer antigen of L523S as taught by Wang et al. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent any evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is (571)272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joanne Hama can be reached on 571-272-2911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Dunston/
Primary Examiner
Art Unit 1636